Alabama Medicaid DUR Board Meeting
Minutes
October 24, 2007

Attendees: Jimmy Jackson, Kevin Royal, Gurinder Doad, Bernie Olin, Kevin Green, Christina Faulkner, Rhonda Harden, Daniel Mims, Tiffany Minnifield, Clemice Hurst, Kelli Littlejohn, Paula Thompson

Absent: Robert Moon, Michael Gosney, Rob Colburn, Jerome Harrison, Denise Thornley-Brown

Paula Thompson, Chairman, called the meeting to order at 1:00pm.

Review and Adoption of Minutes of July 25, 2007 meeting: Paula Thompson asked if there were additions, deletions, or changes to the minutes of the July 25, 2007 meeting. No changes or additions were brought to the attention of the Board. Paula Thompson asked for a motion to approve the minutes as presented. Kevin Green made a motion. Bernie Olin seconded the motion. A voice vote was unanimous to accept the minutes as presented.

Prior Authorization and Overrides Update: Christina Faulkner began the Prior Authorization and Overrides Update by stating that the reports for May, June, July and August were presented in the meeting materials. In the interest of time, however, she stated that she would review only the August reports unless otherwise requested by the Board. For the month of August Christina reported 9,657 manual requests and 12,265 electronic requests. On the Monthly Help Desk Report for August, Christina noted an average wait time per call of 12 seconds and longest wait time of two minutes six seconds. On the Prior Authorization and Override Response Time Ratio, Christina stated that Medicaid requested that HID report on response times of less than eight hours. HID responded to 84.81% of manual prior authorizations and 84.95% of manual overrides in less than two hours. She reported that HID responded to 93.53% of manual prior authorizations and 93.39% of manual overrides in less than four hours. Christina reported a response time of less than eight hours for 98.63% of prior authorizations, 93.99% of overrides, 93.95% of manual prior authorizations, 93.99% of manual overrides and 98.24% overall.

Christina continued the Prior Authorizations and Overrides Update by directing the board members' attention to the Cost Management Analysis Reports beginning on page 42. On the Top 25 Drugs Based on Total Claims from 07/16/07-08/15/07, Christina stated that the top five drugs for the time period were hydrocodone with acetaminophen, Singulair, amoxicillin, alprazolam and Protonix. Discussion followed regarding the possible reduction of hydrocodone prescriptions due to the PDM Program. On the Top 25 Drugs Based on Total Claims Cost from 07/16/07-08/15/07, the top five drugs were Singulair,

Seroquel, Risperdal, Protonix and Abilify. The Board requested that additional information be provided at a later date regarding the relatively high rate of Singulair use. Specifically, they asked to see numbers of recipients with a diagnosis of either asthma or allergic rhinitis.

On the Top 15 Therapeutic Classes by Total Cost of Claims from 07/16/07-08/15/07 report, Christina noted the top five classes: antipsychotic agents, anticonvulsants/miscellaneous, hemostatics, antidepressants and proton pump inhibitors.

Program Summary Review: Christina Faulkner began the review of the Program Summary on page 45 of the meeting manual by going over the 6 Month Assessment covering the time period January 1 through June 30, 2007. She reported a prescription claims cost of $207,681,489.14; 3,531,677 prescriptions; 395,616 total recipients; 191,273 average recipients per month and an average paid per prescription of $58.81. Christina began the Cost Management Analysis on page 46 by reviewing the cost per claim over the last year. On page 49, the Drug Analysis, she reported 61% generic and 26.53 % brand with no generic available. The Board requested that a list of drugs contained within the brand multi source category be provided at the next DUR meeting. 11.69% were brand where generic was available and 69% were "other."

Intervention Activity Report/Cycle Cost Savings Report: For the RDUR Intervention Letter Activity Report, Christina called the board members' attention to page 50. For the June 2007 intervention cycle (asthma), she reported 320 profiles reviewed, 306 letters generated and 301 letters sent. Fifty seven letters were for underutilization of long-term asthma controllers, 147 were for disease state management and five were for inappropriate use of long-acting beta agonists. For the July intervention cycle (asthma), Christina reported 64 profiles reviewed, 69 letters generated, and 69 letters sent. For the August intervention cycle (asthma), she reported 110 profiles reviewed, 131 letters generated and 129 letters sent. For the September intervention cycle (asthma), she reported 72 profiles reviewed, 67 letters generated and 67 letters sent. As of the printing of the meeting manual, 105 responses had been received. Forty eight of 77 physicians indicated that they found the RDUR letters "useful" or "extremely useful". Christina reminded the board members that the asthma intervention will continue through December 2007.

ProDUR Criteria: Christina Faulkner reviewed the low-dose antipsychotic prospective DUR criteria. The Alabama Medicaid Agency and HID recommended several changes to the criteria based on FDA dosing guidelines. Christina explained that some drugs were excluded because the recommended low-dose was not measurable. Christina presented each group of criteria and the board members briefly discussed the guidelines. A voice vote was taken and was unanimous to accept the recommended criteria. The new ProDUR criteria will not be implemented until after the implementation of Medicaid's new MMIS system.

RetroDUR Criteria: Christina reviewed 23 sets of RDUR criteria which will be added to the base set. Several changes to the criteria were discussed and suggested by the

Board. Tiffany Minnifield instructed board members to complete ballots for the criteria. After discussion it was decided by the Board that the ESA topic would be removed from consideration due to the difficulty in tracking.

Medicaid Pharmacy Update: Tiffany Minnifield reminded board members to turn in their criteria ballots. She then called their attention to member folders containing updated drug lists, updated PDL Reference Tool and travel vouchers. She also stated that the folders contained minutes from the most recent P & T meeting and recent Alerts. Ms. Minnifield also pointed out the Alert regarding tamper resistant prescription pads contained in the folder. She stated that dates of implementation for the tamper resistant requirement have changed. As of April 1, 2008, one qualifying characteristic must be met on prescriptions and that by October 1, 2008, all three characteristics must be present on all Medicaid covered prescriptions. Ms. Minnifield announced that the next quarterly seminar will be held in Huntsville. The continuing education portion of the seminar entitled "Heart Failure," will be presented by Paula Thompson. She announced that Synagis season is October 1 through March 31. She also announced that effective January 1, 2008 the brand prescription limit will be increased to five brands per recipient per month. Ms. Minnifield directed the board members attention to the ballots for vice chair contained in the meeting packets. She stated that Jerome Harrison had respectfully requested that his name be withdrawn from consideration for the position. She instructed members to complete ballots.

Kelli Littlejohn welcomed Gurinder Doad, M.D. to the DUR Board. Dr. Doad practices family medicine in Section, AL.

P & T Committee Update: Clemice Hurst presented a brief update of the P & T Committee. She stated that the last P & T meeting was held on August 22. At that meeting, the committee reviewed the anti-infective agents. She stated that the committee recommended that Relenza and Tamiflu be preferred during the influenza season, October 1, 2007 through March 31, 2008. The next P & T Committee meeting will be held November 14. The agenda includes review of behavioral medications, Alzheimer's agents, ADHD agents, anxiolytics/sedative hypnotics and antidepressants.

Next Meeting Date: After discussion and agreement among members, Tiffany Minnifield announced that the next DUR Board meeting will be held on Wednesday, January 23, 2008 at 1:00pm.

Paula Thompson asked if there was any further business to be brought before the Board. There being none, she asked for a motion to adjourn. Jimmy Jackson made a motion to adjourn. Rhonda Harden offered a second to the motion. Chairman Thompson adjourned the meeting at 2:32pm.

ALABAMA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS

Recommended Criteria	*Approved*	*Approved As Amended*	*Rejected*
1. Duloxetine / Therapeutic Appropriateness Alert message: The safety and efficacy of Cymbalta (duloxetine) in pediatric patients have not been established. Anyone considering the use of duloxetine in a child or adolescent must balance the potential risks with the clinical need. Conflict Code: TA – Therapeutic Appropriateness Drug/Diseases Util A Util B Util C Duloxetine Age Range: 0 - 18 years of age References: Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007. Facts & Comparisons, 2007 Updates. Cymbalta Prescribing Information, May 2007, Eli Lilly and Company.	___√___	_____	_____
2. Venlafaxine / Therapeutic Appropriateness Alert Message: The safety and efficacy of Effexor/Effexor XR (venlafaxine) in the pediatric population have not been established. Anyone considering the use of venlafaxine in a child or adolescent must balance the potential risks with the clinical need. Conflict Code: TA – Therapeutic Appropriateness Drug/Diseases Util A Util B Util C Venlafaxine Age Range: 0 - 18 years of age References: Facts & Comparisons, 2007 Updates. Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007. Clinical Pharmacology, Gold Standard, 2007. Effexor XR Prescribing Information, June 2007, Wyeth Pharmaceuticals, Inc.	___√___	_____	_____
3. Citalopram / Therapeutic Appropriateness Alert Message: The safety and efficacy of Celexa (citalopram) in pediatric patients have not been established. Two placebo-controlled trials in 407 children with major depressive disorder (MDD) have been conducted with citalopram, and the data were not sufficient to support a claim for use in pediatric patients. Anyone considering the use of citalopram in a child or adolescent must balance the potential risks with the clinical need. Conflict Code: TA – Therapeutic Appropriateness Drug/Diseases Util A Util B Util C Citalopram Age Range: 0 – 18 years of age References: Facts & Comparisons, 2007 Updates. Celexa Prescribing Information, May 2007, Forest Laboratories, Inc.	___√___	_____	_____

Recommended Criteria	*Approved*	*Approved As Amended*	*Rejected*

4. Escitalopram / Therapeutic Appropriateness ____√____ _____ _____

Alert Message: The safety and efficacy of Lexapro (escitalopram) in pediatric patients have not been established. One placebo-controlled trial in 264 pediatric patients with major depressive disorder (MDD) has been conducted with escitalopram, and the data were not sufficient to support a claim for use in children. Anyone considering the use of escitalopram in a child or adolescent must balance the potential risks with the clinical need.
Conflict Code: TA – Therapeutic Appropriateness
Drug/Diseases

Util A	Util B	Util C
Escitalopram		

Age Range: 0 – 18 years of age
References:
Lexapro Prescribing Information, May 2007, Forest Laboratories, Inc.
Facts & Comparisons, 2007 Updates.
Clinical Pharmacology, Gold Standard, 2007.

5. Fluoxetine / Therapeutic Appropriateness ____√____ _____ _____

Alert message: The safety and efficacy of fluoxetine in pediatric patients younger than 8 years of age with major depressive disorder (MDD) and younger than 7 years of age with obsessive compulsive disorder (OCD) have not been established. Fluoxetine is not approved for any other indications in the pediatric population. Anyone considering the use of fluoxetine in a child or adolescent must balance the potential risks with the clinical need.
Conflict Code: TA – Therapeutic Appropriateness
Drug/Diseases

Util A	Util B	Util C
Fluoxetine		

Age Range: < 7 years of age
References:
Facts & Comparisons, 2007 Updates.
Prozac Prescribing Information, May 2007 Eli Lilly and Company.
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007.

This will catch anyone taking fluoxetine under 7 years of age for any diagnosis.

6. Fluoxetine / Therapeutic Appropriateness ____√____ _____ _____

Alert Message: The safety and efficacy of fluoxetine in the pediatric population for conditions other than major depressive disorder (MDD) and obsessive compulsive disorder (OCD) have not been established. Fluoxetine is approved for use in pediatric patients 7 years of age and older with OCD and 8 years of age and older with MDD. Anyone considering the use of fluoxetine in a child or adolescent must balance the potential risks with the clinical need.
Conflict Code: TA – Therapeutic Appropriateness
Drug/Diseases

Util A	Util B	Util C (Negating)
Fluoxetine		Major Depressive Disorder Obsessive Compulsive Disorder

Age Range: 7- 18 years of age
References:
Facts & Comparisons, 2007 Updates.
Prozac Prescribing Information, May 2005 Eli Lilly and Company.

This will catch anyone taking fluoxetine between the ages of 7 and 18 years of age without a diagnosis of MDD or OCD.

Recommended Criteria	*Approved*	*Approved As Amended*	*Rejected*

7. Paroxetine / Therapeutic Appropriateness ___√___ _____ _____

Alert Message: The safety and efficacy of paroxetine in pediatric patients have not been established. Three placebo-controlled trials in 752 pediatric patients with major depressive disorder (MDD) have been conducted with paroxetine, and the data were not sufficient to support a claim for use in pediatric patients. Anyone considering the use of paroxetine in a child or adolescent must balance the potential risks with the clinical need.
Conflict Code: TA – Therapeutic Appropriateness
Drug/Diseases

Util A	Util B	Util C
Paroxetine		

Age Range: 0 -18 years of age
References:
Facts & Comparisons, 2007 Updates,
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007.
Paxil/Paxil CR Prescribing Information, July 2006, GlaxoSmithKline.

8. Sertraline / Therapeutic Appropriateness _____ ___√____ _____

Diagnoses removed from Column B as marked

Alert Message: The safety and efficacy of Zoloft (sertraline) in the pediatric population for the treatment of depression, panic disorder, PTSD, PMDD, or social anxiety disorder have not been established. Sertraline is approved in pediatric patients 6 years of age and older for obsessive compulsive disorder (OCD). Anyone considering the use of sertraline in a child or adolescent must balance the potential risks with the clinical need.
Conflict Code: TA – Therapeutic Appropriateness
Drug/Diseases

Util A	Util B	Util C (Negating)
Sertraline	~~Depression~~	Obsessive Compulsive Disorder
	~~Panic Disorder~~	
	~~Post Traumatic Stress Disorder~~	
	~~Premenstrual Dysphoria Disorder~~	
	~~Social Anxiety Disorder~~	

Age Range: 6-17 years of age
References:
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007.
Facts & Comparisons, 2007.
Zoloft Prescribing Information, Sept. 2006, Pfizer.

This criterion will hit on anyone receiving Zoloft who is between 6 - 17 years of age, with an unapproved diagnosis (Util B) but without an approved diagnosis of OCD (Util C). Patients 6 – 17 are approved for treatment with Zoloft for OCD, so we do not want theses patients to hit (negate OCD icd-9)
Problem: This will exclude children under 6. So we will do another criterion (below) that will identify patients under six on Zoloft. Zoloft is not approved for patients less than 6 years of age.

Recommended Criteria	*Approved*	*Approved As Amended*	*Rejected*

9. Sertraline / Therapeutic Appropriateness ___√___ _____ _____

Alert Message: The safety and efficacy of Zoloft (sertraline) for the treatment of obsessive compulsive disorder (OCD) in pediatric patients less than 6 years of age have not been established. Anyone considering the use of sertraline in a child or adolescent must balance the potential risks with the clinical need.
Conflict Code: TA – Therapeutic Appropriateness
Drug/Diseases

Util A	Util B	Util C (Negating)
Sertraline		

Age Range: < 6 years of age
References:
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007.
Facts & Comparisons, 2007.
Zoloft Prescribing Information, Sept. 2006, Pfizer.

10. Fluvoxamine / Therapeutic Appropriateness ___√___ _____ _____

Alert Message: The safety and efficacy of fluvoxamine in pediatric patients younger than 8 years of age have not been established. Anyone considering the use of fluvoxamine in a child or adolescent must balance the potential risks with the clinical need.
Conflict Code: TA – Therapeutic Appropriateness
Drug/Diseases

Util A	Util B	Util C
Fluvoxamine		

Age Range: 0 – 7 years of age
References:
Facts & Comparisons, 2007 Updates.
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007.
Clinical Pharmacology, Gold Standard 2007.

11. Symbyax / Therapeutic Appropriateness ___√___ _____ _____

Alert Message: The safety and efficacy of Symbyax (fluoxetine/olanzapine) in pediatric patients have not been established. Anyone considering the use of the combination product fluoxetine/olanzapine in a child or adolescent must balance the potential risks with the cinical need.
Conflict Code: TA – Therapeutic Appropriateness
Drug/Diseases

Util A	Util B	Util C
Symbyax		

Age Range: 0 – 18 years of age
References:
Facts & Comparisons, 2007 Updates.
Symbyax Prescribing Information, May 2007, Eli Lilly and Company.

Recommended Criteria	*Approved*	*Approved As Amended*	*Rejected*

12. Antidepressants / Therapeutic Appropriateness _____ ___√____ _____

Alert Message: All antidepressant-containing medications **may** increase the risk of suicidal thinking and behaviors (suicidality) in children, adolescents, and young adults. Patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior especially during the initial months of drug therapy, or at times of dose changes.

*Add Symbyax to Util A Column
*Wording changes as indicated in bold type

Conflict Code: TA – Therapeutic Appropriateness

Drug/Diseases

Util A	Util B	Util C
Isocarboxazid		
Phenelzine		
Tranylcypromine		
Imipramine		
Amitriptyline		
Nortriptyline		
Desipramine		
Protriptyline		
Fluvoxamine		
Amoxapine		
Trimipramine		
Doxepin		
Maprotiline		
Trazodone		
Bupropion		
Fluoxetine		
Clomipramine		
Sertraline		
Paroxetine		
Venlafaxine		
Nefazodone		
Citalopram		
Mirtazapine		
Escitalopram		
Duloxetine		
Symbyax		

Age Range: 0 – 24 years of age

References:

FDA News: FDA Proposes New Warning About Suicidal Thinking, Behavior in Young Adults Who Take Antidepressant Medications, May 2, 2007. Available at: http://www.fda.gov/bbs/topics/NEWS/2007/NEW01624.html

Recommended Criteria	*Approved*	*Approved As Amended*	*Rejected*

13. Antibiotics / Therapeutic Appropriateness ___√___ _____ _____

Alert Message: The use of antibiotics during the first year of life has been associated with an increased risk of developing childhood asthma. The risk increases with the use of multiple courses of antibiotics and the use of broad-spectrum antibiotics. This risk may be reduced by the judicious and appropriate prescribing of antibiotics, particularly avoiding the use of broad-spectrum cephalosporins.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Disease:

Util A	Util B	Util C
Penicillins		
Cephalosporins		
Monobactams		
Quinolones		
Fluoroquinolones		
Tetracyclines		
Macrolides		
Ketolides		
Oxazolidinones		
Aminoglycosides	Oral	
Sulfonamides		
Bacitracin		
Metronidazole		
Nitrofurans		
Methenamines		
Folate Antagonists		

Age Range: 0 – 1 year of age

References:

Kozyrskyj A, Ernst P, Becker AB, Increased risk of childhood asthma from antibiotic use in early life, Chest. 2007;131(6):1753-1759.

Marra F, Lynd L, Coombes M, et al., Does antibiotic exposure during infancy lead to development of asthma? Chest. 2006;126:610-618.

Johnson CC, Ownby DR, Alford SH, et al., Antibiotic exposure in early infancy and risk of childhood atopy. The Journal of Allergy and Clinical Immunology, June 2005. Vol. 115, Issue 6:1218-1224.

14. Codeine / Pregnancy ____√____ _____ _____

Alert Message: Nursing infants may be at an increased risk of morphine overdose if their mothers are taking codeine-containing products and are ultra-rapid metabolizers of codeine. If codeine use is necessary in nursing mothers prescribe the lowest effective dose for the shortest amount of time. Inform mothers receiving codeine of the potential risks and signs of morphine overdose in themselves and their infants.

Conflict Code: MC – Drug (Actual) Disease Precaution

Drugs/Disease

Util A	Util B	Util C (Negating)
Codeine	Pregnancy	Miscarriage
	Lactation	Abortion

References:

FDA Public Health Advisory: Use of Codeine by some Breastfeeding Mothers may lead to Life-threatening Side Effects in Nursing Babies. August 17, 2007. Available at: http://www.fda.gov/cder/drug/advisory/codeine.htm

Recommended Criteria	*Approved*	*Approved As Amended*	*Rejected*

15. Selzentry / Nonadherence ___√___ _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma levels and partial suppression of viral load leading to the development of resistance, HIV progression, and increased mortality.
Conflict Code: LR - Nonadherence
Drugs/Disease

Util A	Util B	Util C
Maraviroc		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.

Cheever LW, Chapter V: Adherence to HIV Therapies. In: A Guide to Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/AIDS Bureau, US Department of Health and Human Services.
http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

16. Selzentry /Therapeutic Appropriateness ___√___ _____ _____

Alert Message: Selzentry (maraviroc) is FDA approved to be used in combination with other antiretroviral agents to treat adult patients infected with only CCR5-tropic HIV-1 detectable, who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents. There is insufficient data to recommend monotherapy with this agent.
Conflict Code: TA – Therapeutic Appropriateness
Drugs/Disease

Util A	Util B	Util C (Negating)
Maraviroc		All other Antiretrovirals

References:
Selzentry Prescribing Information, August 2007, Pfizer Labs.

17. Selzentry /Cardiovascular Events ___√___ _____ _____

Alert Message: Selzentry (maraviroc) should be used with caution in patients at increased risk for cardiovascular events. In clinical studies, more cardiovascular events, including myocardial ischemia and/or infarction, were observed in patients who received maraviroc as compared to placebo (1.3% vs. 0%).
Conflict Code: TA – Therapeutic Appropriateness
Drugs/Disease

Util A	Util B	Util C
Maraviroc	Cardiovascular Problems	

References:
Selzentry Prescribing Information, August 2007, Pfizer Labs.

Recommended Criteria	*Approved*	*Approved As Amended*	*Rejected*

18. Selzentry /Liver Impairment ___√___ _____ _____

Alert Message: Selzentry (maraviroc) has been linked to hepatotoxicity that may be preceded by a systemic allergic reaction (e.g., pruritic rash, eosinophilia, or elevated IgE). Discontinuation of maraviroc should be considered in any patient with signs and symptoms of hepatitis, or with increased liver transaminases combined with rash or other systemic symptoms. Caution is advised if maraviroc is used in patients with pre-existing liver dysfunction or who are co-infected with hepatitis B or C.
Conflict Code: TA – Therapeutic Appropriateness **(Black Box Warning)**
Drugs/Disease

Util A	Util B	Util C (Negating)
Maraviroc		

References:
Selzentry Prescribing Information, August 2007, Pfizer Labs.

19. Selzentry / High Dose ___√___ _____ _____

Alert Message: The recommended dose of Selzentry (maraviroc) for patients receiving concomitant therapy with NRTIs, tipranavir/ritonavir, nevirapine, and other drugs that are not strong CYP3A inhibitors or CYP3A inducers is 300 mg twice daily.
Conflict Code: HD – High Dose
Drugs/Disease

Util A	Util B	Util C (Negating)
Maraviroc		Strong CYP3A Inhibitors Ritonavir, Atazanavir, Indinavir, Saquinavir, Nelfinavir, Clarithromycin, Telithromycin Ketoconazole, Itraconazole, Nefazodone Strong CYP3A Inducers Carbamazepine, Rifampin, Phenobarbital, Phenytoin, Efavirenz

Max Dose: 600mg/day
References:
Selzentry Prescribing Information, August 2007, Pfizer Labs.
FDA Center for Drug Evaluation and Research, Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers. Available at: http://www.fda.gov/CDER/drug/drugInteractions/tableSubstrates.htm

20. Selzentry / High Dose _____ ___√___ _____

Alert Message: Selzentry (maraviroc) is metabolized by the CYP3A isoenzyme and patients receiving concomitant therapy with protease inhibitors (except tipranavir/ritonavir), delavirdine, ketoconazole, itraconazole, clarithromycin, or other strong CYP3A inhibitors (e.g., nefazodone and telithromycin) should receive a reduced dose of 150 mg of maraviroc twice daily.

***Change Util C list to Util B,**
***Add inducers to Util C**
(Added items indicated in bold type)

Conflict Code: HD – High Dose
Drugs/Disease

Util A	Util B	~~Util C (Inculsive)~~	**Util C**
Maraviroc	**Protease Inhibitors (except tipranavir/ritonavir)**	~~Protease Inhibitors (except tipranavir/ritonavir)~~	**Efavirenz**
	Delavirdine	~~Delavirdine~~	**Rifampin**
	Ketoconazole	~~Ketoconazole~~	**Carbamazepine**
	Itraconazole	~~Itraconazole~~	**Phenobarbital**
	Clarithromycin	~~Clarithromycin~~	**Phenytoin**
	Nefazodone	~~Nefazodone~~	
	Telithromycin	~~Telithromycin~~	

Max Dose: 300 mg/day
References:
Selzentry Prescribing Information, August 2007, Pfizer Labs.

Recommended Criteria	*Approved*	*Approved As Amended*	*Rejected*

21. Selzentry / High Dose ____√____ _____ _____

Alert Message: Selzentry (maraviroc) is metabolized by the CYP3A isoenzyme and patients receiving concomitant treatment with CYP3A inducers (e.g., efavirenz, rifampin, carbamazepine, phenobarbital, and phenytoin) without a strong inhibitor should receive a dose of 600 mg of maraviroc twice daily.
Conflict Code: HD – High Dose
Drugs/Disease

Util A	Util B	Util C (Negating)
Maraviroc	Efavirenz	Protease Inhibitors (except tipranavir/ritonavir)
	Rifampin	Delavirdine
	Carbamazepine	Ketoconazole
	Phenobarbital	Itraconazole
	Phenytoin	Clarithromycin
		Telithromycin
		Nefazodone

Max Dose: 1200 mg/day
References:
Selzentry Prescribing Information, August 2007, Pfizer Labs.

22. Selzentry / Renal Impairment ____√____ _____ _____

Alert Message: Selzentry (maraviroc) should be used with caution in patients with renal impairment, particularly in those with concurrent use of a CYP3A inhibitor and a CrCl < 50 mg/mL. Approximately 25% of maraviroc is renally eliminated and impairment may lead to increased drug concentrations and risk of dose-related adverse effects (e.g., dizziness and postural hypotension). Patients should be monitored for adverse effects.
Conflict Code: DB – Drug/Drug Marker and/or Diagnosis
Drugs/Disease

Util A	Util B	Util C
Maraviroc	Renal Impairment	
	Lanthanum	
	Sevelamer	
	Doxercalciferol	
	Paricalcitol	
	Calcitriol	

References:
Selzentry Prescribing Information, August 2007, Pfizer Labs.

23. Selzentry / Hypotension _____ ____√____ _____

***Add diuretics to Util B**

Alert Message: Selzentry (maraviroc) should be used with caution in patients with a history of postural hypotension or who are on concomitant medication known to lower blood pressure. The frequency of postural hypotension is increased at higher than recommended doses.
Conflict Code: DB – Drug/Drug Marker and/or Diagnosis
Drugs/Disease

Util A	Util B	Util C
Maraviroc	Postural Hypotension	
	Beta Blockers	
	Calcium Channel Blockers	
	ACE Inhibitors	
	ARBs	
	Anti-adrenergic Agents	
	Vasodilator Antihypertensives	
	Diuretics	

References:
Selzentry Prescribing Information, August 2007, Pfizer Labs.

The minutes of the October 24, 2007 DUR Board Meeting have been reviewed and approved as submitted.

Carol H. Steckel, Commissioner (X) Approve ( ) Deny 12/4/07 Date

Kathy Hall, Deputy Commissioner (X) Approve ( ) Deny 11-29-07 Date

Robert Moon, M.D., Medical Director (X) Approve ( ) Deny 11-21-07 Date